K001055

510(K) SUMMARY

Date: March 31, 2000

Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Contact: Dawn E. Frazer
Vice President
Regulatory Affairs & Quality Assurance
(978) 670-2422 x243
dfrazer@physiometrix.com

Subject Device: Model 4300 PSArray EEG Electrode Set

Classification: ~~Class II,~~ CFR 21 Part 882.1320, Cutaneous Electrodes

Intended Use: The Physiometrix PSArray EEG Electrode is applied directly to the patient's skin to enable recording of electrophysiologic signals (such as EEG).

Description: The Physiometrix Model 4300, PSArray EEG Electrode Set, is a single-use, disposable, pre-gelled electrode array. The PSArray is comprised of seven (7) electrodes, three (3) on the forehead (Fp1, FpZ', and Fp2), two (2) on the midline of the scalp (CZ and PZ) and two at ears (A1 and A2). The electrode is packaged with one (1) electrode per pouch, ten (10) pouches per box and four (4) boxes per case.

Forehead Electrodes
The forehead electrodes are mounted in a triangular shaped basepad comprised of polyethylene foam coated with a pressure sensitive adhesive. The electrode pad is an area of silver/silver chloride ink that is connected to cable connector by a silver ink trace. An electrolyte gel is held in place over the electrode pad by a open-cell polyurethane sponge located in wells created by the foam basepad. The electrolyte gel was selected for its low impedance. No prepping is required to achieve adequate impedance levels for operation of the PSA4000.

Scalp Electrodes
The scalp electrodes are comprised of silver/silver-chloride ink printed electrode pad, pointed dimples formed in the electrode pad and a reservoir that is filled with gel. Once the electrode has been applied to the patient, a slight pressure is applied to the reservoir in order to dispense the gel and part the hair. The pointed dimples separate the hair at the electrode site and allow the gel to flow to the scalp. The scalp electrodes are held in place by downward action created by coils in substrate.

Ear Electrodes
The ear electrodes are commercially available cloth electrodes die cut to a custom shape to enable application to ears (K991105).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Ms. Dawn E. Frazer
Vice President, Regulatory Affairs
and Quality Assurance
Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
North Billerica, Massachusetts 01862

Re: K001055
Trade Name: Model 4300 PSArray EEG Electrode Set
Regulatory Class: II
Product Code: GXY
Dated: March 31, 2000
Received: April 3, 2000

Dear Ms. Frazer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001055

INDICATIONS FOR USE STATEMENT

Applicant:	Physiometrix, Inc.
510(k) Number (if known)	~~Not assigned~~ K001055
Device Name	Model 4300 PSArray EEG Electrode Set
Indications For Use	The Physiometrix PSArray EEG Electrode is applied directly to the patient's skin to enable recording of electrophysiologic (such as EEG) signals.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lo Cicero

Sign-Off)
General Res
mber K001055

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)